

Exhibit A

Part 1

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June 27, 2005

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OF COUNSEL

Morris M. Shuster
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*Attorneys admitted to
practice in Delaware

**VIA INTERNATIONAL REGISTERED MAIL,
RETURN RECEIPT REQUESTED**

Laboratories Fournier, S.A.
Attention: General Counsel
42 Rue de Longvie
21300 Chenove
France

Re: *Painters District Council No. 30, et. al. v. Abbott Laboratories, et. al.,*
C.A. No. 05-360

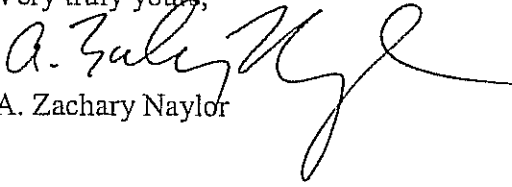
Vista Healthplan, Inc, et. al.. v. Abbott Laboratories, et. al.,
C.A. No. 05-365

Allied Services Division Welfare Fund, et. al. v. Abbott Laboratories,
et. al., C.A. No. 05-394

To Whom it May Concern:

Enclosed please find copies of the Summonses and Complaints in connection with the above-captioned matters pending in the United States District Court, District of Delaware. The Summonses and Complaints were served on the Delaware Secretary of State pursuant to 10 Del. C. § 3104. Such service is effective as if personally served on you within this state.

Very truly yours,



A. Zachary Naylor

AZN/ce
Enclosures

HAVERFORD OFFICE

One Haverford Centre
361 West Lancaster Avenue
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UNITED STATES DISTRICT COURT

District of

Delaware

PAINTERS DISTRICT COUNCIL No. 30
HEALTH and WELFARE FUND, and RICHARD
G. WILDE, on behalf of themselves and
all others similarly situated,

SUMMONS IN A CIVIL CASE

ABBOTT LABORATORIES, FOURNIER INDUSTRIE
ET SANTE, and LABORATORIES FOURNIER, S.A.

CASE NUMBER: 05-360 KAJ

TO: (Name and address of Defendant)

Laboratories Fournier, S.A. c/o Secretary of State
State of Delaware 401 Federal Street, Suite 4 Dover, DE 19901
Pursuant to 10 Del. C. §3104

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

A. Zachary Naylor
Chimicles & Tikellis LLP
One Rodney Square
P.O. Box 1035
Wilmington, DE 19899

an answer to the complaint which is served on you with this summons, within 20 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

PETER T. DALLEO

JUN 22 2005

CLERK

DATE

Evette Watson
(By) DEPUTY CLERK

FD-40 (Rev. 8/01) Summons in a Civil Action

RETURN OF SERVICE

Service of the Summons and complaint was made by me ⁽¹⁾	DATE June 23, 2005
NAME OF SERVER (PRINT) Mark Messina	TITLE Process Server
Check one box below to indicate appropriate method of service	

- ☐ Served personally upon the defendant. Place where served: _____
- ☐ Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.
Name of person with whom the summons and complaint were left: _____
- ☐ Returned unexecuted: _____

☒ Other (specify): Served: Laboratories Fournier, S.A. c/o Delaware Secretary of State, Townsend Building, Dover, DE copies thereof were accepted by Mickey Troubeparis at 1:46 p.m.

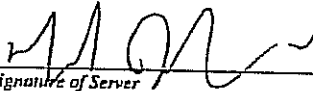
STATEMENT OF SERVICE FEES

TRAVEL	SERVICES	TOTAL
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DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on 6/24/05
Date


Signature of Server

Tristate Courier & Carriage
824 N. Market ST., Wilmington, DE 19801
Address of Server

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

UNITED STATES DISTRICT COURT

District of

Delaware

PAINTERS DISTRICT COUNCIL No. 30
HEALTH and WELFARE FUND, and RICHARD
G. WILDE, on behalf of themselves and
all others similarly situated,

SUMMONS IN A CIVIL CASE

ABBOTT LABORATORIES, FOURNIER INDUSTRIE
ET SANTE, and LABORATORIES FOURNIER, S.A.

CASE NUMBER: 05-360 KAJ

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Laboratories Fournier, S.A. c/o Secretary of State
State of Delaware 401 Federal Street, Suite 4 Dover, DE 19901
Pursuant to 10 Del. C. §3104

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

A. Zachary Naylor
Chimicles & Tikellis LLP
One Rodney Square
P.O. Box 1035
Wilmington, DE 19899

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PETER T. DALLEO

JUN 22 2005

CLERK

DATE

Evette Watson
(By) DEPUTY CLERK

AD 440 (Rev. 8/01) Summons in a Civil Action

RETURN OF SERVICE

Service of the Summons and complaint was made by me ⁽¹⁾	DATE June 23, 2005
NAME OF SERVER (PRINT) Mark Messina	TITLE Process Server
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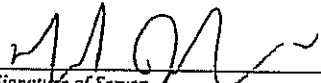
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FILED
CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE
2005 JUN -6 PM 1:09

PAINTERS DISTRICT COUNCIL No.30
HEALTH and WELFARE FUND, and
RICHARD G. WILDE, on behalf of
themselves and all others similarly situated,
Plaintiffs,

v.

ABBOTT LABORATORIES, FOURNIER
INDUSTRIE ET SANTE, and
LABORATOIRES FOURNIER, S.A.,

Defendants.

Civil Action No. 05 - 360

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiffs Painters District Council No.30 Health and Welfare Fund ("the Fund") and Richard G. Wilde, individually and on behalf of all others similarly situated, for their complaint against defendants Abbott Laboratories ("Abbott"), Fournier Industrie et Sante, and Laboratoires Fournier, S.A. (collectively "Fournier" and collectively with Abbott "Defendants"), upon knowledge as to themselves and their own acts, and upon information and belief as to all other matters, allege as follows:

NATURE OF THE ACTION

1. This class action is brought under the federal antitrust laws and the antitrust and/or deceptive practice statutes of twenty-three states and the District of Columbia to remedy anti-competitive actions by Defendants to foreclose generic competition for cholesterol-lowering drugs that contain the active pharmaceutical ingredient ("API") fenofibrate. Abbott and Fournier market, and have marketed, fenofibrate products under the brand-name TriCor®. In the past year alone, Abbott and Fournier total sales of TriCor® products exceeded of \$750 million.

2. Abbott and Fournier have implemented and are pursuing a scheme to unlawfully maintain and prolong their monopoly position in the market for fenofibrate products. This scheme abuses aspects of the complex health care delivery system and regulatory environment to deprive doctors and consumers of an opportunity to choose generic versions of fenofibrate formulations. The scheme keeps a step ahead of would-be generic competitors by delaying generic competition for its initial fenofibrate formulations, shifting the market to “new and improved” formulations that are altered only to avoid bioequivalence with the earlier formulations, and then withdrawing their initial formulations from healthcare databases. The act of withdrawing their initial formulations from healthcare databases is unnecessary to market their “new and improved” formulations, and has the purpose and effect of erecting substantial barriers to entry on would-be generic competitors by ensuring that once a generic company is able to launch a competitive fenofibrate product, it will have to do so without the benefits of generic classification that would have been available but for the scheme. Because the old formulation branded product no longer exists, the new competitive product: (i) cannot be marketed as a generic; and (ii) cannot be substituted for Abbott’s and Fournier’s next generation TriCor® products.

3. The components of Abbott’s and Fournier’s unlawful and anticompetitive pattern and practice of conduct to thwart generic entry of fenofibrate products, as alleged more fully below, includes the following:

- (a) Abbott and Fournier bring a particular formulation of a TriCor® product to market;
- (b) When generic competitors develop and seek to sell lower-cost bioequivalent generic versions of the TriCor® product, Abbott and Fournier engage in a range of

practices which have the purpose and effect of delaying the launch of competitive generic products until after they are able to launch a new formulation of their TriCor® product;

(c) During the period when Abbott's and Fournier's delay tactics block competitive generic drug rivals from the market, Abbott and Fournier exploit their monopoly in fenofibrate products to charge supracompetitive prices for TriCor® products. Those prices are far higher than the prices generic competitors would charge if they were able to sell their bioequivalent versions of TriCor® products;

(d) Once market entry by competitive generic drug products appears imminent, Abbott and Fournier begin selling a *new* formulation of a TriCor® product. The new formulation is the same medicine, used for the same indications, as the existing formulation. Abbott and Fournier take affirmative steps to convert customers from the existing formulation to the new formulation before the competitive generic products are available for sale;

(e) Despite Abbott's and Fournier's efforts to convert them, not all patients or doctors would switch from the old formulation to the new formulation. Accordingly, Abbott and Fournier have taken affirmative steps to deprive them of a choice and, at the same time, eliminate a generic market for the old formulation before the competitive generic versions are available to the public. In 2002, Abbott and Fournier removed its brand reference for TriCor® capsules from the National Drug Data File® ("NDDF"), so that the branded drug code reference no longer exists for purposes of generic substitution laws or for purposes of health care providers' pharmaceutical benefit programs. Defendants stand poised to repeat this maneuver with its market shift to new tablet formulations.

4. As a result of this scheme, once a generic manufacturer is able to start selling a product that is bioequivalent to the old TriCor® formulation, and therefore could be substituted

by a pharmacist for the old product — the market for that product has been switched to the new product. Because the would-be generic formulation is bioequivalent to the old brand formulation, pharmacists and others cannot legally substitute the product for the new TriCor® product, even though the products are indicated for the same uses. The product switch and the withdrawal of the NDDF code effectively eliminates generic competition which otherwise would have arisen.

5. Abbott's and Fournier's conduct unreasonably restrains competition. If Abbott and Fournier simply launched their new products, consumers would benefit from the existence of competition in sales of fenofibrate products. Instead, because Abbott and Fournier have improperly staved off generic competition and could potentially continue to do so indefinitely, Plaintiff and members of the Class have been forced to pay supracompetitive prices for and are deprived of choices among fenofibrate products.

6. This class action is brought on behalf of all end-payors (*i.e.*, consumers and other persons or entities that pay for prescription for family members, employees or insureds) who purchased or paid for fenofibrate products, including TriCor® products since April 9, 2002. In Count I, Plaintiff seeks a judgment pursuant to §16 of the Clayton Act, 15 U.S.C. § 26, enjoining the continuation of Defendants' unlawful monopolistic practices in violation of §2 of the Sherman Act, 15 U.S.C. §2. Neither Plaintiff nor the Class seek any relief under §4 of the Clayton Act, 15 U.S.C. § 15.

7. In Count II, Plaintiffs and the Class also seek damages for Defendants' violations of the antitrust and/or deceptive practice statutes of Arizona, California, District of Columbia, Florida, Iowa, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, South

Dakota, Tennessee, Vermont, West Virginia and Wisconsin (collectively, the "Indirect Purchaser States").

8. In Count III, Plaintiffs and the Class seek equitable remedies as to Defendants' unjust enrichment.

JURISDICTION AND VENUE

9. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 22 and 26. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. §1367(a).

10. Venue is proper within this District under 15 U.S.C. §22 and 28 U.S.C. §1391(b) because Defendants are found or transact business within this District, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District.

11. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(d)(2), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interests and costs, and is a class action in which "any member of a class of plaintiffs is a citizen of a state different from any defendant."

TRADE AND COMMERCE

12. At all relevant times, TriCor® was manufactured by Defendants and was thereafter sold, shipped and transported across state lines to United States customers located outside the state of manufacture. In connection with the purchase and sale of TriCor®, monies, as well as contracts, bills, and other forms of business communications and transactions, were transmitted in a continuous and uninterrupted flow across state lines. Various means and devices were used to effectuate the Defendants' actions alleged herein, including the United States mail,

interstate travel, interstate telephone commerce, and other forms of interstate electronic communications. The activities of Defendants alleged herein were within the flow of, and have substantially affected, interstate commerce.

THE PARTIES

Plaintiffs

13. a. The Fund is located at St. Charles, Illinois and is an “employee welfare benefit plan” and an “employee benefit plan” within the Employee Retirement Income Security Act (ERISA), 29 USC §§ 1002(1), 1002(3), 1003(a). As such, Plaintiff is a legal entity entitled to bring suit in its own name pursuant to 29 USC§ 1132(d). Plaintiff is a not-for-profit trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health care benefits to participant-workers, who are employed under various collective bargaining agreements, and to their dependents. The Fund has paid all or part of the cost of its participants’ purchases of fenofibrate products during the Class Period.

b. Plaintiff Richard Wilde is an individual residing in Dunellen, New Jersey. During the class period, Wilde has taken TriCor and has paid for a portion of its cost.

Defendants

14. Defendant Abbott is a corporation organized, existing, and doing business under the laws of the state of Illinois. Its office and principal place of business is located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott is engaged principally in the development, manufacture, and sale of pharmaceuticals and health care products and services. Abbott had sales of \$19.7 billion in 2004. Abbott operates in 130 countries and has facilities in 14 states.

15. Defendants Fournier Industrie et Sante, formerly known as Fournier Innovation et Synergic, and Laboratoires Fournier, S.A., are French corporations having their principal place of

business at 42 Rue de Longvie, 21300 Chenove, France. Abbott is the licensee from Fournier of the five patents listed in the Orange Book for TriCor® products.

RELEVANT MARKET

16. The relevant product market in which to assess the anticompetitive effect of Abbott's and Fournier's conduct is the market for fenofibrate products, which consists of TriCor® products and generic bioequivalent versions of TriCor® products. Upon final approval from the FDA, generic fenofibrate products will be reasonably interchangeable, and will have a strong cross-elasticity of demand, with TriCor® products. At all relevant times, Defendants' market share in the relevant product and geographic markets was and between 95% and 100%.

17. The relevant geographic market is the United States as a whole (for Counts I and III) and the Indirect Purchaser States (for Count II).

FACTUAL ALLEGATIONS

The Federal Scheme For Approval of Generic Drugs.

18. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, (the "FFDCA") approval by the FDA is required before a new drug can be manufactured and sold. Approval for a new drug, often referred to as a "pioneer drug," must be sought by filing a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are often covered by patents and marketed under a brand name.

19. Generic drugs are drugs which the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is bioequivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating. According to the FDA, a bioequivalent drug rated "AB" may be

used and substituted interchangeably with the referenced branded drug.

20. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be purchased from a licensed pharmacist. The pharmacist must, in turn, fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug which has been approved by the FDA is available. Once a physician writes a prescription for a brand-name drug such as TriCor® capsules, that prescription can be filled only with the drug named or its AB-rated generic equivalents. Only generic drugs which carry the FDA's "AB" rating may be substituted by a pharmacist for a doctor's prescription for a brand-name drug.

21. If an AB-rated generic formulation of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most prescription drug benefit plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by prescription drug benefit plans, the pharmacist will offer the consumer the choice of purchasing the AB-rated generic at a lower price.

22. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office ("CBO") concluded that the purchase of generic drugs saved consumers and third party payors between \$8-10 billion in a single year. A report prepared by the Government Accounting Office in August 2000 observed that: "Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices

than brand-name drugs.”

23. A branded drug loses a significant portion of its market share to generic competitors less than a year after the introduction of generic competition, even if the brand-name manufacturer lowers prices to meet competition. In testimony before Congress, a representative from the Pharmaceutical Research and Manufacturers of America (a brand-name pharmaceutical manufacturers’ trade association), confirmed that “in most cases, sales of pioneer medicines drop as much as 75 percent within weeks after a generic copy enters the market.”

24. The 1998 CBO study also concludes that the average price of brand-name drugs facing generic competition is less than the average price of brand-name drugs without generic competition.

The Hatch Waxman Amendments

25. In 1984, Congress enacted the Hatch-Waxman Act to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. 21 U.S.C. § 355.

26. The Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application (“ANDA”) that incorporates by reference the safety and effectiveness data developed and previously submitted in the NDA process by the company that manufactured the pioneer drug.

27. The FDA maintains and publishes *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”), which lists all prescription drugs approved for use in the United States and the patents, if any, covering those drugs.

28. For each patent applicable to the pioneer drug listed in the Orange Book, an ANDA applicant must certify whether the proposed generic drug would infringe that patent and,

if not, why not in accordance with FFDCA Section 355(j)(2)(A)(vii).

29. An ANDA filer must make one of four certifications in accordance with FFDCA Section 355(j)(2)(A)(vii):

- I. that no patent for the pioneer drug has been filed with the FDA;
- II. that the patent for the pioneer drug has expired;
- III. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or
- IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the generic company's proposed product (a "Paragraph IV Certification").

30. If an ANDA includes a Paragraph IV Certification, the applicant must notify the pioneer drug patent owner of the certification.

31. Upon receiving notification of a Paragraph IV Certification, the pioneer drug patent owner has 45 days under the Hatch-Waxman Act to initiate a patent infringement lawsuit against the ANDA applicant (the "45 day window"). If no lawsuit is initiated during the 45 day window, the process for FDA approval of the generic product continues.

32. If a patent infringement suit is commenced within the 45 day window, FDA final approval of the ANDA is automatically stayed until the earliest of: (a) the expiration of the patent; (b) the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification (the "30 month stay"); or (c) a final judicial determination of non-infringement or patent invalidity.

33. The first filer of an ANDA with a Paragraph IV Certification is eligible for a 180-day period in which to market its generic version on an exclusive basis (the "180-day exclusivity period").

34. The 180-day exclusivity period is triggered by either: (a) commercial marketing of the generic product, or (b) a final court decision that the patent at issue is either invalid or not infringed.

35. Prior to the expiration of the 30 month stay, the FDA may grant “tentative” approval of an ANDA once it determines that all the criteria for “final” approval have been satisfied.

36. The Hatch-Waxman Act expressly permits the FDA to grant final approval to the first filed ANDA, and an ANDA applicant with FDA approval may market its generic product in the United States while the patent infringement lawsuit remains unresolved.

37. If a patent is listed in the Orange Book, the pioneer drug patent holder need only file a patent infringement lawsuit within the 45 day window in order to block FDA approval of an ANDA applicant’s generic drug from entering the market for up to 30 months.

38. If there are only Paragraph III certifications relative to a patent listed in the Orange Book, an ANDA is eligible for approval as soon as the patent expires, without delays associated with patent infringement litigation.

39. The Medicare Prescription Drug Improvement and Modernization Act of 2003, signed by President Bush on December 8, 2003, changed certain provisions of the Hatch-Waxman Act to curtail abuses by pharmaceutical manufacturers, such as precluding multiple 30-month stays.

Fenofibrate Products

40. Pharmaceutical products with the API fenofibrate reduce high levels of low-density lipoprotein cholesterol (“LDL-C”), sometimes referred to as “bad cholesterol,” and triglycerides by promoting the dissolution and elimination of fat particles in the blood.

Fenofibrate products also increase levels of high-density lipoprotein cholesterol ("HDL-C"), sometimes referred to as "good cholesterol," and reduce LDL-C in patients with primary hypercholesterolemia (high bad cholesterol) or mixed dyslipidemia (high bad cholesterol and high triglycerides). Fenofibrate products are also effective at reducing triglycerides in patients with hypertriglyceridemia (high triglycerides).

41. On February 9, 1998, Abbott received final approval for NDA No. 019304 for 67 mg fenofibrate capsules. On June 30, 1999, Abbott received final approval for 134 mg and 200 mg fenofibrate capsules. In connection with fenofibrate capsules, Abbott submitted to the FDA for listing in the Orange Book Patent No. 4,984,726 (the "'726 patent'"), which was granted on January 23, 1990 to Fournier and exclusively licensed to Abbott in 1997.

Generic Manufacturers Apply To Market Fenofibrate Products

42. On December 14, 1999, Novopharm Ltd. filed an ANDA for 67 mg fenofibrate capsules (the "Capsule ANDA"). Novopharm sought approval to market its fenofibrate capsule product prior to the expiration of the '726 patent. Novopharm certified that its product did not infringe the '726 patent, and duly and timely notified Abbott of its ANDA. The ANDA was amended on March 31, 2000 and November 27, 2000 to include the 200 mg and 134 mg strength capsules.

43. Other generic manufacturers subsequently sought to market fenofibrate capsules, including Impax Laboratories, Inc. (ANDA filed May 9, 2000) and Reliant Pharms Inc. (NDA filed December 1, 2003).

44. On April 7, 2000, Abbott and Fournier sued Novopharm in the United States District Court for the Northern District of Illinois for infringement of the '726 patent based on Teva's Capsule ANDA for 67 mg and 200 mg fenofibrate capsules. Abbott's and Fournier's

lawsuit triggered the automatic 30-month stay under the Hatch-Waxman Act, preventing the FDA from granting final approval to Teva's Capsule ANDA. In April 2000, Novopharm was acquired by Teva and thus became a Teva entity. Abbott and Fournier also sued Impax in the Northern District of Illinois, giving rise to a 30-month stay.

Abbott's and Fournier's First Market Switch: Capsules to Tablets

45. Abbott also held NDA No. 021203 for 54 mg and 160 mg fenofibrate tablets, which the FDA approved on September 4, 2001. Abbott, and, through its licensing agreement, Fournier, thereafter sold 54 mg and 160 mg fenofibrate tablets in the United States under the brand name TriCor®. Abbott's sales of TriCor® tablets have since accounted for over 95% of all sales of fenofibrate products, and 100% of all fenofibrate tablet sales, in the United States. For the twelve months ending September 2004, these products had sales in the United States in excess of \$750 million.

46. After the FDA approved Abbott's NDA for fenofibrate tablets, Abbott and Fournier took affirmative steps to destroy the market for generic fenofibrate capsules. Abbott and Fournier removed the fenofibrate capsule code from the National Drug Data File® ("NDDF"), and they removed (or "obsoleted") TriCor® brand fenofibrate capsules from the market. NDDF is a widely accepted database provided by First Databank, Inc. that includes drug descriptive and pricing information with an extensive array of clinical decision-support modules. This electronic drug information encompasses every drug approved by the FDA, including generic alternatives, and is used throughout the healthcare industry. By removing TriCor® capsules from the NDDF, the branded drug code reference no longer exists for purposes of generic substitution laws or for purposes of health care providers' pharmaceutical benefit programs.

47. When they removed the capsules from the market, Abbott and Fournier also changed Abbott's sales force and stopped detailing the capsule formulation in the market. By removing the capsule code from the NDDE, Abbott and Fournier rendered the TriCor® capsule code, to which Teva's capsules would have been compared, obsolete.

**Teva's Pyrrhic Victory on Fenofibrate Capsules – Approval
For a Product That Could No Longer Be Marketed as a Generic**

48. On March 19, 2002, the Illinois court granted Teva's motion for summary judgment of noninfringement of the '726 patent, clearing the way for Teva to market its fenofibrate capsule product. On March 26, 2003, the Illinois court granted Impax's motion for summary judgment of non-infringement as well.

49. On April 9, 2002, as a result of the noninfringement decision, Teva received final FDA approval to market its 200 mg (as well as 134 mg) fenofibrate capsule products, and tentative FDA approval to market its 67 mg fenofibrate capsule products. Teva began to sell its 200 mg and 134 mg fenofibrate capsule products in April 2002. As the first filer of a Capsule ANDA with a Paragraph IV certification, Teva was granted a six-month exclusivity period during which the FDA would not grant final approval to another fenofibrate capsule ANDA. During an exclusivity period for a blockbuster drug such as TriCor® capsules, Teva could reasonably expect to make well more than \$100 million in sales at prices substantially less than the price for branded TriCor® capsules.

50. But, because of Abbott's and Fournier's anticompetitive tactics, the favorable decision and the exclusivity period proved to be a pyrrhic victory for Teva. Because Abbott and Fournier removed TriCor® capsules from NDDE, there was no longer a brand reference drug for Teva's fenofibrate capsules. Abbott's and Fournier's only purpose in removing the capsule code

from the NDDF was to foreclose generic competition from Teva and other generic manufacturers in the fenofibrate product market. Had the capsule code been maintained in the NDDF, there would still have been a reference for which Teva's generic capsules could have been substituted. Without Abbott's and Fournier's branded TriCor® capsule code as a reference, however, and without the continuation of Abbott's capsules in the marketplace, there was no longer a market for generic fenofibrate capsule products. Accordingly, most of the fenofibrate capsules that Teva had shipped to its customers were returned. Teva was effectively blocked from the market as a generic competitor in the fenofibrate market.

51. On October 7, 2002, the statutory 30-month stay on FDA approval of Teva's Capsule ANDA for 67 mg fenofibrate capsules ended, allowing Teva to enter the then-defunct capsule market with that dosage. On October 23, 2003, Impax was granted final approval to market its fenofibrate capsule products.

Teva Files ANDA to Market Fenofibrate Tablets

52. Frustrated by Abbott's and Fournier's anticompetitive steps to preclude the marketing of generic fenofibrate capsules, Teva next sought to market generic fenofibrate tablets. On June 17, 2002, Teva filed with the FDA an ANDA for its generic fenofibrate 54 mg and 160 mg tablets (the "Tablet ANDA"). In connection with its Tablet ANDA, Teva submitted a Paragraph IV certification that the ANDA did not infringe the '726 Patent, as well as two additional patents, U.S. Patent No. 6,074,670 (the "670 Patent") and U.S. Patent No. 6,277,405 (the "405 Patent"). On August 21, 2002, Teva gave notice to Abbott and Fournier of the filing of the Tablet ANDA and the Paragraph IV certification made therein.

53. In response to Teva's Tablet ANDA and August 21, 2002 letter, Abbott and Fournier filed patent infringement action Civil Action No. 02-1512, which asserts that Teva's

Tablet ANDA infringes the '726 Patent, the '670 Patent, and the '405 Patent.

54. Abbott's and Fournier's patent infringement action against Teva concerning the '726 Patent, the '670 Patent, and the '405 Patent triggered an automatic 30-month stay under the Hatch-Waxman Act that prevented the FDA from granting final approval to Teva's Tablet ANDA for so long as the statutory stay remains in effect.

55. On July 23, 2003, Abbott and Fournier listed U.S. Patent No. 6,589,552 (the "552 Patent") in the Orange Book for TriCor® 54 mg and 160 mg tablets.

56. By July 29, 2003, Teva supplemented its Tablet ANDA by filing a Paragraph IV certification to the '552 Patent. By July 29, 2003 Teva gave notice to Abbott and Fournier of the filing of its Paragraph IV certification to the '552 Patent.

57. In response to Teva's Paragraph IV certification to the '552 Patent, Abbott and Fournier filed patent infringement action Civil Action No. 03-847 on August 29, 2003. In their action, Abbott and Fournier claim that Teva's Tablet ANDA infringes the '552 Patent. Abbott's and Fournier's patent infringement action against Teva concerning the '552 triggered *another* 30-month automatic stay period under the Hatch-Waxman Act. This successive 30-month stay commenced and, absent a court decision, will continue in effect more than one year after the first 30-month stay that went into effect with the filing of the first action, C.A. No. 02-1512.

Abbott Submits NDA for New Tablet Formulations

58. On October 29, 2003, Abbott submitted NDA No. 021656 to the FDA for its new version of TriCor® fenofibrate tablets in 48 mg and 145 mg dosage forms. Abbott and Fournier did not seek FDA approval for this new formulation product until after they knew that Teva had developed generic fenofibrate tablets and was seeking approval to sell those tablets in the United States.

59. On December 12, 2003, Abbott and Fournier listed U.S. Patent No. 6,0652,881 (the "881 Patent") in the Orange Book for TriCor® 54 mg and 160 mg tablets.

60. On December 17, 2003, Teva supplemented its Tablet ANDA by filing a Paragraph IV certification to the '881 Patent. On December 17, 2003, Teva gave notice to Abbott and Fournier of the filing of its Paragraph IV certification to the '881 Patent.

61. In response to Teva's Paragraph IV certification to the '881 Patent, Abbott and Fournier filed patent infringement action Civil Action No. 04-0047 on January 22, 2004. In their action, Abbott and Fournier claim that Teva's Tablet ANDA infringes the '881 Patent. Fortunately, because of the December 2003 amendments to the Hatch-Waxman Act, another 30-month stay was not available.

Teva Granted Tentative Approval For 54 mg and 160 mg Fenofibrate Tablets

62. On March 5, 2004, the FDA granted tentative approval to Teva's Tablet ANDA. By granting tentative approval, the FDA indicated that Teva's fenofibrate 54 mg and 160 mg tablets are bioequivalent to TriCor® tablets of the same dosage strengths. Due to the successive 30-month stays resulting automatically from Abbott's and Fournier's filing and maintenance of their patent infringement actions against Teva concerning Teva's Tablet ANDA, the FDA was legally precluded from granting final approval to Teva's Tablet ANDA until the stays expire or a court enters judgment in Teva's favor.

Abbott's and Fournier's Second Market Switch

63. On November 5, 2004, Abbott announced that it had received FDA approval to market the 48 mg and 145 mg TriCor® fenofibrate tablets. The new version tablets replace Abbott's 54 mg and 160 mg tablet dosage forms and are indicated for the exact same uses as the 54 mg and 160 mg tablet dosage forms.

64. Abbott and Fournier have already begun marketing their new TriCor® tablet products, and they have ceased supplying the market with the 54 mg and 160 mg TriCor® tablets. The supply of Abbott's and Fournier's 54 mg and 160 mg TriCor® tablets soon disappeared and Abbott and Fournier removed the brand reference code from the NDDF.

65. On May 16, 2005, Teva announced that the FDA granted final approval for the Company's Tablet ANDA for fenofibrate tablets, 54 mg and 160 mg.

66. With final approval of Teva's Tablet ANDA, the purpose of Abbott's and Fournier's patent infringement litigation — *i.e.*, to delay generic entry for another market switch — had run its course and served its purpose. Accordingly, on the same day that Teva announced final approval of its ANDA, May 16, 2005, Abbott and Fournier informed the judge presiding over the patent infringement actions that “they no longer wish to prosecute their consolidated patent infringement action against Teva and Impax.”

**The Effects of Defendants' Anti-Competitive Conduct
on the United States Market for Fenofibrate Products**

67. The purpose of Defendants' anti-competitive conduct is to obtain and maintain monopoly power in the market for fenofibrate products and their generic bioequivalents. But for the anticompetitive actions alleged herein, generic versions of TriCor® capsules would have been available to consumers in April 2002. When Teva launched its fenofibrate capsules in April 2002, however, no branded reference was available because Abbott had taken the unprecedented step of removing its brand reference code from the NDDF.

68. By removing TriCor® capsules from the NDDF, the branded drug code reference no longer exists for purposes of generic substitution laws or for purposes of health care providers' pharmaceutical benefit programs. For example, had Abbott not withdrawn TriCor®

capsules from the NDDF, a pharmacist filling a prescription written for TriCor® capsules after April 2002 would have been advised by a code reference in the database that a lower cost generic version of the drug was available. Thus, the pharmacist could, and often must, substitute the generic version for TriCor® capsules in filling the prescription. Similarly, prescription benefit plans that provide for tiered co-payment arrangement are designed to steer consumers to lower cost generic drugs by requiring higher co-payments for branded drugs, *e.g.*, a branded co-payment might be \$25, but only \$10 for the generic version of the same drug. These incentives result in a brand name drug quickly losing a significant portion of its market share soon after the introduction of generic competition, even if the brand name manufacturer lowers its price to meet competition. This is the very generic competition that Congress sought to facilitate when it adopted the Hatch-Waxman Act in 1984.

69. For fenofibrate products, however, Abbott and Fournier have gamed the system to undermine the purposes of the Hatch-Waxman Act and preclude consumer access to lower-cost generic fenofibrate products. By withdrawing TriCor® capsules from the NDDF and ensuring that a code reference for the branded drug no longer exists for purposes of the U.S Healthcare system, a prescription for TriCor® capsules *cannot be filled by the pharmacist at all, not even with a bioequivalent substitute marketed by Teva*. Similarly, an insured consumer attempting to fill a prescription for TriCor® capsules will not be able to do so, and will not have the option of substituting a generic version for a lower co-payment.

70. Because the code reference for TriCor® capsules does not exist, Teva could not sell its fenofibrate capsules as a generic drug. In fact, most of the fenofibrate capsules that Teva shipped after the launch in 2002 were subsequently returned by customers because they could not be sold. Teva was forced to market its fenofibrate capsules as a branded product (under the trade

name Lofibra®) without the benefits of a generic classification for purposes of generic substitution laws or lower prescription benefit co-payments. Teva, like most generic manufacturers, does not employ an extensive marketing department like brand-name manufacturers and Lofibra® sales have been negligible (in the range of about \$4 million per year), barely scratching the surface of Abbott's and Fournier's fenofibrate monopoly. Other generic manufacturers have received FDA final approval to market fenofibrate capsules (Impax Labs on October 27, 2003 and Reliant Pharms on November 30, 2004), but they face the same barriers as Teva in penetrating Abbott's and Fournier's fenofibrate monopoly. By foreclosing the ability of generic manufacturers to market generic products, Abbott's and Fournier's anticompetitive acts imposed significant barriers to market entry on its would-be generic competitors and allowed Defendants to maintain supracompetitive prices for their fenofibrate products.

71. Defendants repeated this maneuver with the market shift to new tablet formulations. Abbott's and Fournier's conduct also will ensure that even if prescriptions for the 54 mg and 160 mg tablet formulations are written, no generic substitutions will be allowed. In order to accomplish this, Abbott and Fournier have ceased distribution of their 54 mg and 160 mg tablet formulations to the market and removed the reference code in the NDDF for their 54 mg and 160 mg tablet formulations. Without this reference code, it is illegal for a pharmacist to substitute a generic alternative of the 54 mg and 160 mg formulations for any prescription for the 54 mg and 160 mg tablet formulations.

72. Abbott's and Fournier's removal of the reference code in the NDDF for its 54 mg and 160 mg tablet formulations also will make it more expensive for any patients to use Teva's fenofibrate tablets in the event that any doctors continue to write prescriptions for 54 mg and/or

160 mg fenofibrate formulations. Patients will be forced to pay higher co-payment amounts for Teva's 54 mg or 160 mg fenofibrates tablets when there is no reference code for Abbott's and Fournier's TriCor® 54 mg or 160 mg tablets in the NDDF than they would be required to pay for generic manufacturers' product if Abbott and Fournier maintained the reference in the NDDF. This is because, without a reference code in the NDDF for TriCor® 54 mg or 160 mg tablets, generic manufacturers' tablets will be treated as branded product rather than a generic product if listed in the NDDF, which would lead prescription benefit providers to require higher co-payments.

73. When one attempts to purchase a fenofibrate product, the current impact of Abbott's and Fournier's anticompetitive scheme is apparent. For example, online retailer drugstore.com sells most all branded and generic drugs, and encourages generic substitution with immediate price comparisons.

Generic vs. Brand Medications

Generic medicines are approved for use by the Food and Drug Administration (FDA) and are therapeutically equivalent to brand name products. In almost all cases, generics work just as well as their brand-name siblings and often cost considerably less.

Most states allow pharmacists to substitute a generic when appropriate and when you and your doctor authorize it. Our pharmacy is located in New Jersey, so we substitute generic drugs recognized as interchangeable under New Jersey law. If you and your doctor have authorized the use of generic medicines, our pharmacy will substitute your prescription with the generic equivalent.

<http://www.drugstore.com/cat/10661/tmpl/default.asp?catid=15610&trx=9885&trxp1=15610&trxp2=topic&trxp3=15574>. An inquiry for a branded drug with an available generic version, such as Cipro®, is reported as follows:

	30 tablets	90 tablets
Cipro	\$148.99	\$433.97
<u>tablets</u>		save
<u>500MG</u>		\$13.00
Generic Ciprofloxacin HCl	\$121.71	\$360.64
<u>tablets</u>		\$your best
<u>500MG</u>		value

Source: drugstore.com (May 19, 2005).

74. An inquiry for "trikor" [on May 19, 2005], however, produces only the following results:

	30 tablets	90 tablets
Tricor	\$33.99	\$94.97
<u>tablets</u>		save
<u>48MG</u>		\$7.00

	30 tablets	90 tablets
Tricor	\$89.99	\$254.96
<u>tablets</u>		save
<u>145MG</u>		\$15.01

There is no reference to TriCor® capsules (which no longer exist), TriCor® tablets in 54 mg, 67 mg or 160 mg strength (since Abbott has already choked off the supply), generic versions of those products, or Lofibra® capsules, which is not a generic bioequivalent to the tablets.

75. A inquiry for "fenofibrate" will also bring up a reference to Lofibra® capsules as a branded drug without a generic alternative, as follows:

	30 capsules	90 capsules
Lofibra	\$26.24	\$69.29
<u>capsules</u>		save
<u>67MG</u>		\$9.43

	30 capsules	90 capsules
Lofibra	\$48.29	\$133.34
<u>capsules</u>		save
<u>134MG</u>		\$11.53

	30 capsules	90 capsules
Lofibra	\$73.49	\$205.79
<u>capsules</u>		save
<u>200MG</u>		\$14.68

76. As a result of Defendants' anti-competitive conduct, Plaintiff and the Class have been financially injured. First, Plaintiff and the Class have never had the opportunity to pay for lower-cost generic versions of fenofibrate products. Second, while Defendants have maintained their monopoly for fenofibrate products and generic equivalents, Plaintiff and the Class have paid and reimbursed supra-competitive and artificially high prices for TriCor® products.

77. Defendants had and have no legitimate justification, economic or otherwise, for committing the violations of law alleged herein. Abbott's and Fournier's conduct in ending sales of certain strengths or formulations of their TriCor® tablets and their TriCor® capsules is purely private conduct. Removing a product reference from the NDDF does not involve any governmental petitioning activity.

CLASS ALLEGATIONS

78. Plaintiffs bring this class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, sub-sections 23(a) and 23(b)(2) and/or (b)(3), on behalf of a class defined as follows:

All persons or entities in the United States and its territories who purchased, paid and/or reimbursed for fenofibrate products, including TriCor® tablets and TriCor® capsules, intended for consumption by themselves, their families, or their members, employees or insureds (the "Class") during the period from April 9, 2002 through such time in the future as the effects of Defendants' illegal conduct, as alleged herein, have ceased (the "Class Period"). Excluded from the Class are all Defendants and their respective subsidiaries and affiliates, all governmental entities, and all persons or entities that purchased fenofibrate products: (i) for purposes of resale, or (ii) directly from any of the Defendants.

Count II applies to purchases of fenofibrate products in the Indirect Purchaser States.

79. The members of the Class are so numerous that joinder of all members is

impracticable. Purchasers of fenofibrate products during the Class Period number in the millions nationally, and there are, at a minimum, thousands of fenofibrate purchasers in each state.

80. Defendants' unlawful, anti-competitive and inequitable methods, acts and trade practices have targeted and affected all members of the Class in a similar manner, *i.e.*, they have been overpaying for fenofibrate products due to the absence of competing generic versions of TriCor® tablets and TriCor® capsules in the marketplace, and will continue to pay supra-competitive prices so long as Defendants' scheme continues. Among the questions of law and fact common to the Class are:

- (a) whether, under common principles of antitrust and trade practice law, Defendants' methods, practices and acts, as alleged herein, including, but not limited to, withdrawing the reference code in the NDDF for TriCor® capsules, violate federal and state antitrust and/or consumer protection laws;
- (b) whether Defendants have monopolized and attempted to monopolize the market for fenofibrate products;
- (c) whether Defendants intentionally and unlawfully excluded competitors and potential competitors from the market for fenofibrate products and generic bio-equivalents of TriCor® formulations;
- (d) whether Plaintiffs and members of the Class are entitled to equitable and/or injunctive relief;
- (e) the amount of the overcharges or amounts paid or reimbursed by members of the Class for fenofibrate products over and above the amounts they would have paid or reimbursed in a competitive market unaffected by Defendants' illegal acts as alleged herein; and
- (f) whether under common principles of unjust enrichment, Defendants unjustly enriched themselves to the detriment of Plaintiffs and the Class, entitling Plaintiffs and the Class to disgorgement of all monies resulting therefrom.

81. Plaintiffs' claims are typical of those of the Class they represent because Plaintiffs and all of the Class members were injured and continue to be injured and/or threatened with

injury in the same manner by Defendants' unlawful, anti-competitive and inequitable methods, acts and practices, *i.e.*, they have paid and continue to pay supra-competitive prices for fenofibrate products and will continue to be forced to do so until the Relevant Market is truly competitive and prices have stabilized to competitive levels.

82. Plaintiffs will fully and adequately protect the interests of all members of the Class. Plaintiffs have retained counsel who are experienced in antitrust and consumer class action litigation. Plaintiffs have no interests which are adverse to, or in conflict with, other members of the Class.

83. The questions of law and fact common to the members of the Class predominate over any questions which may affect only individual members.

84. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty likely to be encountered in the management of this action that would preclude its maintenance as a class action.

85. In addition, Defendants have acted and refused to act, as alleged herein, on grounds generally applicable to the Class.

COUNT I

(INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT)

86. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

87. As alleged above, Defendants knowingly and willfully engaged in a course of conduct designed to unlawfully maintain and prolong their monopoly position in the market for fenofibrate products in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

88. Plaintiffs and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic fenofibrate products, and paying higher prices for TriCor® products than they would have paid in the absence of the antitrust violation. The injury to Plaintiffs and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct. Plaintiffs and members of the Class are threatened with further injuries as a result of Defendants' continuing scheme, as alleged herein.

89. Plaintiffs and the Class seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

COUNT II

(FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES – ASSERTED BY PLAINTIFF WILDE)

90. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

91. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the

Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

e. Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);

f. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;

g. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, *et seq.*, and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;

h. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;

i. Massachusetts: The aforementioned practices by Defendants were and are

in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;

j. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§445.771, *et seq.*, and the Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

k. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

l. Mississippi: The aforementioned practices by Defendants were and are in violation of Miss. Code Ann. §§ 75-21-1, *et seq.*;

m. Nebraska: The aforementioned practices by Defendants were and are in violation of Ne. Rev. Stat. §§ 59-801, *et seq.*;

n. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;

o. New Jersey: The aforementioned practices by Defendants were and are in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9-1, *et seq.*, and the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1, *et seq.*;

p. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

q. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and the New York Deceptive

Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

r. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

s. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

t. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.*, and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

u. Tennessee: The aforementioned practices of Defendants were and are in violation the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*;

v. Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

w. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; and

x. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq.*

92. As a result of the conduct described above, Plaintiffs and the Class have sustained and will continue to sustain substantial losses and damage to their businesses and property in the

form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions of TriCor®, and paying prices for fenofibrate products that were higher than they would have been but for Defendants' improper actions. The full amount of such damages are presently unknown and will be determined after discovery and upon proof at trial.

93. Plaintiffs and the Class seek damages, multiple damages, treble damages, and other damages as permitted by state law, for their injuries caused by these violations pursuant to these statutes.

COUNT III

(FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS)

94. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

95. As a result of their unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Defendants' unlawful acts include, for the reasons alleged above, improperly withdrawing the reference code in the NDDF for TriCor® capsules in order to impose barriers to entry for generic manufacturers seeking to compete in the Relevant Market. Defendants have been unjustly enriched, to the detriment of Plaintiffs and the Class by the receipt of, at a minimum, unlawfully inflated prices and illegal monopoly profits on their sale of TriCor® products. Defendants have benefitted from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains resulting from the overpayments for TriCor® products made by Plaintiff and the Class.

96. Plaintiffs and members of the Class are entitled to the amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiffs and

the Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiffs and the Class members may make claims on a *pro rata* basis.

WHEREFORE, Plaintiffs pray that:

(a) the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, equitable and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages; and declare Plaintiffs as representatives of the Class;

(b) the conduct alleged herein be declared, adjudged and decreed to be in violation of Section 2 of the Sherman Act, of the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment;

(c) Plaintiffs and each member of the Class be awarded damages and, where applicable, treble, multiple, and other damages, according to the laws of the Indirect Purchaser States, including interest;

(d) Plaintiffs and each member of the Class recover the amounts by which Defendants have been unjustly enriched;

(e) Defendants be enjoined from continuing the illegal activities alleged herein;

(f) Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law;

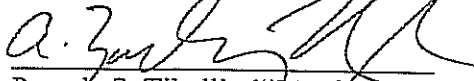
(g) Plaintiffs and the Class be granted such other and further as the Court deems just and necessary.

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury of all issues so triable in this case.

Dated: June 6, 2005

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CIVIL COVER SHEET

JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

(a) PLAINTIFFS PAINTERS DISTRICT COUNCIL
No. 30 HEALTH & WELFARE FUND and
RICHARD G. WILDE

DEFENDANTS ABBOTT LABORATORIES; FOURNIER
INDUSTRIE ET SANTE and LABORATORIES
FOURNIER, S.A.

(b) County of Residence of First Listed Plaintiff Kane County, IL
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE
LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)
Chimicles & Rikellis LLP, One Rodney
Square, Wilmington, DE 19801
(302) 656-2500

Attorneys (If Known)

BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff ☒ Federal Question (U.S. Government Not a Party)
- 2 U.S. Government Defendant ☐ Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | | | | | |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

V. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="checkbox"/> 422 Appeal 28 USC 158 <input checked="" type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS: <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DJWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 1609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Tons to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

☒ Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgement

VI. CAUSE OF ACTION Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
15 U.S.C. § 2
Brief description of cause: Antitrust Action concerning Defendants' monopolizatio
of fenofibrate

VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION DEMAND \$ ☐ CHECK YES only if demanded is complaint:
UNDER F.R.C.P. 23 JURY DEMAND: XIX Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Judge Jordan
DOCKET NUMBER 03-1512; 03-120; 03-288;
03-8472; 03-890; 04-47;
04-48; 05-340;

DATE 6/6/05 SIGNATURE OF ATTORNEY OF RECORD 05-351

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FILED
CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE
2005 JUN -5 PM 1:09

PAINTERS DISTRICT COUNCIL No.30
HEALTH and WELFARE FUND, and
RICHARD G. WILDE, on behalf of
themselves and all others similarly situated,
Plaintiffs,

v.

ABBOTT LABORATORIES, FOURNIER
INDUSTRIE ET SANTE, and
LABORATOIRES FOURNIER, S.A.,
Defendants.

Civil Action No. 05 - 360

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiffs Painters District Council No.30 Health and Welfare Fund ("the Fund") and Richard G. Wilde, individually and on behalf of all others similarly situated, for their complaint against defendants Abbott Laboratories ("Abbott"), Fournier Industrie et Sante, and Laboratoires Fournier, S.A. (collectively "Fournier" and collectively with Abbott "Defendants"), upon knowledge as to themselves and their own acts, and upon information and belief as to all other matters, allege as follows:

NATURE OF THE ACTION

1. This class action is brought under the federal antitrust laws and the antitrust and/or deceptive practice statutes of twenty-three states and the District of Columbia to remedy anti-competitive actions by Defendants to foreclose generic competition for cholesterol-lowering drugs that contain the active pharmaceutical ingredient ("API") fenofibrate. Abbott and Fournier market, and have marketed, fenofibrate products under the brand-name TriCor®. In the past year alone, Abbott and Fournier total sales of TriCor® products exceeded of \$750 million.

2. Abbott and Fournier have implemented and are pursuing a scheme to unlawfully maintain and prolong their monopoly position in the market for fenofibrate products. This scheme abuses aspects of the complex health care delivery system and regulatory environment to deprive doctors and consumers of an opportunity to choose generic versions of fenofibrate formulations. The scheme keeps a step ahead of would-be generic competitors by delaying generic competition for its initial fenofibrate formulations, shifting the market to “new and improved” formulations that are altered only to avoid bioequivalence with the earlier formulations, and then withdrawing their initial formulations from healthcare databases. The act of withdrawing their initial formulations from healthcare databases is unnecessary to market their “new and improved” formulations, and has the purpose and effect of erecting substantial barriers to entry on would-be generic competitors by ensuring that once a generic company is able to launch a competitive fenofibrate product, it will have to do so without the benefits of generic classification that would have been available but for the scheme. Because the old formulation branded product no longer exists, the new competitive product: (i) cannot be marketed as a generic; and (ii) cannot be substituted for Abbott’s and Fournier’s next generation TriCor® products.

3. The components of Abbott’s and Fournier’s unlawful and anticompetitive pattern and practice of conduct to thwart generic entry of fenofibrate products, as alleged more fully below, includes the following:

(a) Abbott and Fournier bring a particular formulation of a TriCor® product to market;

(b) When generic competitors develop and seek to sell lower-cost bioequivalent generic versions of the TriCor® product, Abbott and Fournier engage in a range of

practices which have the purpose and effect of delaying the launch of competitive generic products until after they are able to launch a new formulation of their TriCor® product;

(c) During the period when Abbott's and Fournier's delay tactics block competitive generic drug rivals from the market, Abbott and Fournier exploit their monopoly in fenofibrate products to charge supracompetitive prices for TriCor® products. Those prices are far higher than the prices generic competitors would charge if they were able to sell their bioequivalent versions of TriCor® products;

(d) Once market entry by competitive generic drug products appears imminent, Abbott and Fournier begin selling a *new* formulation of a TriCor® product. The new formulation is the same medicine, used for the same indications, as the existing formulation. Abbott and Fournier take affirmative steps to convert customers from the existing formulation to the new formulation before the competitive generic products are available for sale;

(e) Despite Abbott's and Fournier's efforts to convert them, not all patients or doctors would switch from the old formulation to the new formulation. Accordingly, Abbott and Fournier have taken affirmative steps to deprive them of a choice and, at the same time, eliminate a generic market for the old formulation before the competitive generic versions are available to the public. In 2002, Abbott and Fournier removed its brand reference for TriCor® capsules from the National Drug Data File® ("NDDF"), so that the branded drug code reference no longer exists for purposes of generic substitution laws or for purposes of health care providers' pharmaceutical benefit programs. Defendants stand poised to repeat this maneuver with its market shift to new tablet formulations.

4. As a result of this scheme, once a generic manufacturer is able to start selling a product that is bioequivalent to the old TriCor® formulation, and therefore could be substituted

by a pharmacist for the old product — the market for that product has been switched to the new product. Because the would-be generic formulation is bioequivalent to the old brand formulation, pharmacists and others cannot legally substitute the product for the new TriCor® product, even though the products are indicated for the same uses. The product switch and the withdrawal of the NDDF code effectively eliminates generic competition which otherwise would have arisen.

5. Abbott's and Fournier's conduct unreasonably restrains competition. If Abbott and Fournier simply launched their new products, consumers would benefit from the existence of competition in sales of fenofibrate products. Instead, because Abbott and Fournier have improperly staved off generic competition and could potentially continue to do so indefinitely, Plaintiff and members of the Class have been forced to pay supracompetitive prices for and are deprived of choices among fenofibrate products.

6. This class action is brought on behalf of all end-payors (*i.e.*, consumers and other persons or entities that pay for prescription for family members, employees or insureds) who purchased or paid for fenofibrate products, including TriCor® products since April 9, 2002. In Count I, Plaintiff seeks a judgment pursuant to §16 of the Clayton Act, 15 U.S.C. § 26, enjoining the continuation of Defendants' unlawful monopolistic practices in violation of §2 of the Sherman Act, 15 U.S.C. §2. Neither Plaintiff nor the Class seek any relief under §4 of the Clayton Act, 15 U.S.C. § 15.

7. In Count II, Plaintiffs and the Class also seek damages for Defendants' violations of the antitrust and/or deceptive practice statutes of Arizona, California, District of Columbia, Florida, Iowa, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, South

Dakota, Tennessee, Vermont, West Virginia and Wisconsin (collectively, the "Indirect Purchaser States").

8. In Count III, Plaintiffs and the Class seek equitable remedies as to Defendants' unjust enrichment.

JURISDICTION AND VENUE

9. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 22 and 26. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. §1367(a).

10. Venue is proper within this District under 15 U.S.C. §22 and 28 U.S.C. §1391(b) because Defendants are found or transact business within this District, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District.

11. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(d)(2), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interests and costs, and is a class action in which "any member of a class of plaintiffs is a citizen of a state different from any defendant."

TRADE AND COMMERCE

12. At all relevant times, TriCor® was manufactured by Defendants and was thereafter sold, shipped and transported across state lines to United States customers located outside the state of manufacture. In connection with the purchase and sale of TriCor®, monies, as well as contracts, bills, and other forms of business communications and transactions, were transmitted in a continuous and uninterrupted flow across state lines. Various means and devices were used to effectuate the Defendants' actions alleged herein, including the United States mail,

interstate travel, interstate telephone commerce, and other forms of interstate electronic communications. The activities of Defendants alleged herein were within the flow of, and have substantially affected, interstate commerce.

THE PARTIES

Plaintiffs

13. a. The Fund is located at St. Charles, Illinois and is an “employee welfare benefit plan” and an “employee benefit plan” within the Employee Retirement Income Security Act (ERISA), 29 USC §§ 1002(1), 1002(3), 1003(a). As such, Plaintiff is a legal entity entitled to bring suit in its own name pursuant to 29 USC§ 1132(d). Plaintiff is a not-for-profit trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health care benefits to participant-workers, who are employed under various collective bargaining agreements, and to their dependents. The Fund has paid all or part of the cost of its participants’ purchases of fenofibrate products during the Class Period.

b. Plaintiff Richard Wilde is an individual residing in Dunellen, New Jersey. During the class period, Wilde has taken TriCor and has paid for a portion of its cost.

Defendants

14. Defendant Abbott is a corporation organized, existing, and doing business under the laws of the state of Illinois. Its office and principal place of business is located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott is engaged principally in the development, manufacture, and sale of pharmaceuticals and health care products and services. Abbott had sales of \$19.7 billion in 2004. Abbott operates in 130 countries and has facilities in 14 states.

15. Defendants Fournier Industrie et Sante, formerly known as Fournier Innovation et Synergic, and Laboratoires Fournier, S.A., are French corporations having their principal place of

business at 42 Rue de Longvie, 21300 Chenove, France. Abbott is the licensee from Fournier of the five patents listed in the Orange Book for TriCor® products.

RELEVANT MARKET

16. The relevant product market in which to assess the anticompetitive effect of Abbott's and Fournier's conduct is the market for fenofibrate products, which consists of TriCor® products and generic bioequivalent versions of TriCor® products. Upon final approval from the FDA, generic fenofibrate products will be reasonably interchangeable, and will have a strong cross-elasticity of demand, with TriCor® products. At all relevant times, Defendants' market share in the relevant product and geographic markets was and between 95% and 100%.

17. The relevant geographic market is the United States as a whole (for Counts I and III) and the Indirect Purchaser States (for Count II).

FACTUAL ALLEGATIONS

The Federal Scheme For Approval of Generic Drugs.

18. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, (the "FFDCA") approval by the FDA is required before a new drug can be manufactured and sold. Approval for a new drug, often referred to as a "pioneer drug," must be sought by filing a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are often covered by patents and marketed under a brand name.

19. Generic drugs are drugs which the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is bioequivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating. According to the FDA, a bioequivalent drug rated "AB" may be